FILED
2018 Oct-29 PM 04:57
U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
EASTERN DIVISION

ELIZABETH MORGAN TODD,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NUMBER:**
	)	
PFIZER, INC., a corporation	)	**1:18-cv-01513**
FICTITIOUS DEFENDANTS A–Z, whose names are Unknown to the Plaintiff at this time and whose involvement are detailed herein,	)	
	)	
Defendants.	)	

DEFENDANT PFIZER INC.'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT AND MEMORANDUM IN SUPPORT

Defendant Pfizer Inc. moves to dismiss Plaintiff's Complaint (the "Complaint") for failure to state a claim upon which relief can be granted.

BACKGROUND

Lyrica® is a prescription medication manufactured by Pfizer—and approved by the FDA—for the management of fibromyalgia, among other indications. Fibromyalgia is a chronic disorder that can cause widespread pain, sleep problems, fatigue, distress, and memory and concentration problems. *See Fibromyalgia*, CDC, https://www.cdc.gov/arthritis/basics/fibromyalgia.htm (last visited Oct. 22, 2018).

Plaintiff Elizabeth Morgan Todd alleges that she was prescribed Lyrica to treat her fibromyalgia "in or around August 2008." Compl. ¶¶ 13, 63. She alleges that she used Lyrica "for years" and "suffered severe adverse reaction[s]," including "permanent memory loss" and "cognitive decline." *Id.* ¶ 22.

On September 17, 2018, more than a decade after she was first prescribed Lyrica, Plaintiff filed this Complaint, asserting claims for (1) negligence; (2) violations of the Alabama Extended Manufacturers' Liability Doctrine (AEMLD); (3) breach of express warranty; (4) breach of implied warranties; (5) fraudulent misrepresentation; (6) fraudulent concealment; (7) negligent misrepresentation; (8) fraud and deceit; (9) violation of consumer protection laws; (10) negligence – failure to warn; and (11) negligence – negligent design.

No facts support these claims. Instead, Plaintiff's Complaint is full of conclusory assertions of Pfizer's alleged misconduct in failing to warn of Lyrica's purported ability to cause her claimed injury. Moreover, the scant facts she does plead show that her claims are preempted by federal law under the Food Drug and Cosmetic Act, as other courts in this District have recently held. *McGee v. Boehringer Ingelheim Pharms., Inc.*, No. 4:16-CV-2082-KOB, 2018 WL 1399237, at *3–5 (N.D. Ala. Mar. 20, 2018). Plaintiff's Complaint should therefore be dismissed with prejudice in its entirety.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). To be plausible on its face, the complaint must "contain[] sufficient facts to support a reasonable inference that the defendant is liable for the misconduct alleged." *Gates v. Khokhar*, 884 F.3d 1290, 1296 (11th Cir. 2018). Plausibility requires allegations showing more than a "sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. "This necessarily requires that a plaintiff include factual allegations for each essential element of his or her claim." *GeorgiaCarry.Org, Inc. v. Georgia*, 687 F.3d 1244, 1254 (11th Cir. 2012). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, and unadorned, the-defendant-unlawfully-harmed-me accusation[s], cannot withstand a motion to dismiss." *Odion v. Google Inc.*, 628 F. App'x 635, 637 (11th Cir. 2015) (quoting *Iqbal*, 556 U.S. at 678).

ARGUMENT

I. Plaintiff's Complaint should be dismissed in its entirety because Plaintiff fails to state a plausible claim for relief.

The Court should dismiss Plaintiff's Complaint because she fails to state any plausible claims for relief.

A. Plaintiff has not alleged sufficient facts to support a plausible AEMLD claim (Count 2).

A plaintiff alleging an AEMLD claim must prove: "(1) he suffered injury or damages to himself or his property by one who [sold] a product in a defective condition unreasonably dangerous to the plaintiff, as the ultimate user or consumer, if (a) the seller [was] engaged in the business of selling such a product, and (b) it [was] expected to and [did], reach the user or consumer without substantial change in the condition in which it [was] sold." *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 518 (11th Cir. 2007) (quoting *Morguson v. 3M Co.*, 857 So. 2d 796, 800 (Ala. 2003)).

As the Eleventh Circuit has recognized, "'the adequacy of [a drug's] accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous.'" *Bodie*, 236 F. App'x at 518 (quoting *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984)). Therefore, in a case involving a prescription medication, the AEMLD permits only a failure-to-warn claim. *See, e.g.*, *Barcal v. EMD Serono, Inc.*, No. 5:14-cv-01709-MHH, 2016 WL 1086028, at *3 (N.D. Ala. Mar. 21, 2016) (dismissing design-defect claim); *Cooper v. Bristol-Myers Squibb Co.*, No. 07-885 (FLW), 2013 WL 85291, at *10 (D.N.J. Jan. 7, 2013) (applying Alabama law and dismissing manufacturing defect claim). To the extent Plaintiff's AEMLD claim is based on an alleged design defect or manufacturing defect, the Court should dismiss it.

Plaintiff also fails to state a plausible failure-to-warn claim, the only type of claim the AEMLD would permit with respect to a prescription medication. Plaintiff's putative claim is premised on Pfizer's alleged failure to warn about a risk of cognitive decline from use of Lyrica.[1] This claim requires Plaintiff to plausibly allege, among other things, that Pfizer knew or should have known of this alleged risk before her claimed injury. *See, e.g.*, *Bodie*, 236 F. App'x at 518–19 (citing *Walls v. Alpharma USPD, Inc.*, 887 So. 2d 881, 883 (Ala. 2004)).

No facts show that Pfizer knew about the alleged risk of cognitive impairment at any specific time—much less that Pfizer knew or should have known about this risk before Plaintiff's alleged injury. Plaintiff does not even allege when her injury occurred, but instead alleges only that she was prescribed Lyrica to treat her fibromyalgia "in or around August 2008," and that she "used Lyrica for years." Compl. ¶¶ 13, 22. Those facts are critical to a failure-to-warn claim: Under the AEMLD, a manufacturer "ha[s] no duty to warn of a possible [injury] which it had no reason to suspect might occur."[2] *See Griggs v. Combe, Inc.*, 456 So. 2d 790, 792 (Ala. 1984).

[1] Pfizer reserves its rights with respect to any characterization of Plaintiffs' alleged injury, which remains unclear at this stage of the litigation based on the vague and varied terms used by Plaintiff in her Complaint. In light of the forgoing, Pfizer will use the term, "cognitive impairment" throughout this brief only for ease of reference.

[2] Courts applying Alabama law have recognized that a plaintiff asserting a failure-to-warn claim under the AEMLD must plausibly allege that the manufacturer "knew or should have known that the product could create a danger when used in its intended or customary manner." *Haney v. Eaton Elec., Inc.*, 528 F. Supp. 2d 1262, 1270 (N.D. Ala. Dec. 17, 2007); *see also, e.g.*, *Easterling v.*

At most, Plaintiff has identified a study that discusses certain brain activity, (Compl. ¶ 35), but she makes no clear link to the symptoms she claims to have experienced. Plaintiff likewise has not identified any failure to warn based on Pfizer's knowledge at the time of her alleged injury. Indeed, as with her other allegations, Plaintiff does not allege when this study occurred or whether the study and "[o]ther information" pre-dated her alleged injury. The Court should dismiss Plaintiff's AEMLD claim. *See, e.g.*, *Batchelor v. Pfizer, Inc.*, No. 2:12-CV-908-WKW, 2013 WL 3873242, at *3 (M.D. Ala. July 25, 2013) (dismissing failure-to-warn claim where plaintiff failed to allege whether she took drug before or after FDA required black box warning concerning bone density loss).

B. Plaintiff has not alleged sufficient facts to support any plausible negligence claims.

Plaintiff asserts claims for negligence (Count 1), negligent failure-to-warn (Count 10), and negligent design (Count 11), but none are adequately pleaded.

1. Plaintiff has not stated a viable negligence claim because she has not plausibly alleged that Lyrica is a defective product.

To prevail on a negligence claim, "the Plaintiff must allege[] that the Defendant '(1) breached (2) a duty, which (3) proximately caused (4) plaintiff's

Ford Motor Co., 303 F. Supp. 3d 1211, 1230 (N.D. Ala. Mar. 29, 2018) ("To establish the defendant's duty to warn, the plaintiff must prove that . . . the defendant knew or should have known that the product could create a danger when used in its intended or customary manner." (quoting *Campbell v. Robert Bosch Power Tool Corp.*, 795 F. Supp. 1093, 1097 (M.D. Ala. 1992))), *appeal filed*, No. 18-12914 (11th Cir.).

injury.'" *Miller v. Pfizer Inc.*, No. 4:13-CV-01687-KOB, 2014 WL 2155020, at *4 (N.D. Ala. May 22, 2014) (quoting *E.R. Squibb & Sons, Inc. v. Cox*, 477 So. 2d 963, 969 (Ala. 1985)). Plaintiff's negligence claim here is premised on Pfizer's alleged failure "to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Lyrica." Compl. ¶ 44.

This negligence claim cannot proceed because, as with her AEMLD claim, Plaintiff has not plausibly alleged that Lyrica is a defective product. As the Alabama Supreme Court has recognized, there is a "measure of commonality" between common-law negligence and AEMLD claims. *McMahon v. Yamaha Motor Corp., U.S.A.*, 95 So. 3d 769, 772 (Ala. 2012). "With regard to either an AEMLD claim or a common-law negligence claim," the plaintiff must show "that the product at issue is defective." *Id.* But "[i]n a negligence case," the plaintiff must prove "not only that the product at issue is defective, but *also* that the manufacturer failed to exercise due care in the product's manufacture, design, or sale." *Id.* (emphasis added). Put simply, if the plaintiff has not plausibly alleged a product defect claim under the AEMLD, a negligence claim should likewise fail. That is the case here. *See supra* at 4–6.

Nor does Plaintiff's conclusory assertion satisfy the federal pleading standard. *See Odion*, 628 F. App'x at 637. Plaintiff's negligence claims thus also fail because

she has not alleged sufficient facts that Pfizer failed to exercise due care in Lyrica's manufacture, design or sale to support a plausible negligence claim.

The Court should dismiss Plaintiff's negligence claims.[3]

2. Plaintiff does not plead sufficient facts to support a plausible negligent failure-to-warn claim (Count 10).

As Pfizer has explained, (*supra* at 5–6), Plaintiff has not plausibly alleged that Pfizer knew or should have known of the alleged risk of cognitive impairment before her purported injury. Instead, Plaintiff's negligent failure-to-warn claim relies on the same conclusory allegations as her AEMLD claims and should thus be dismissed. *See, e.g.*, *Employers Ins. Co. of Wausau v. SMS-GHH, Inc.*, No. CV-05-CO-00596-W, 2007 WL 9711501, at *3 (N.D. Ala. July 31, 2007) (dismissing negligence claim based on "the same allegations and evidence" as a dismissed AEMLD claim).

[3] In the Complaint, Plaintiff asserts—in conclusory fashion and with no factual support—a laundry list of other reasons that Pfizer was allegedly negligent. *See, e.g.*, Compl. ¶¶ 42a–u, 45a–h, 51a–o. For example, Plaintiff seems to assert that Pfizer negligently manufactured Lyrica. *See* Compl. ¶¶ 42, 45, 51. But Plaintiff has provided no "meaningful factual allegations" to support these bare negligence claims. *Weldon v. Wash. Nat'l Ins. Co.*, No. 2:13-CV-02209-RDP, 2014 WL 130486, at *2 (N.D. Ala. Jan. 14, 2014). These "naked assertions" are not entitled to the presumption of truth and are insufficient to withstand a motion to dismiss. *See McGee v. Boehringer Ingelheim Pharms., Inc.*, No. 4:16-CV-2082-KOB, 2018 WL 1399237, at *1, 5 (N.D. Ala. Mar. 20, 2018) (describing similar allegations as "a useless set of legal conclusions" and recognizing that a plaintiff must provide "more than an unadorned, the defendant-unlawfully-harmed-me accusation"; "[N]or do pleadings suffice that are based merely upon 'labels or conclusions' or 'naked assertions' without supporting factual allegations.").

3. Plaintiff's negligent design claim (Count 11) should be dismissed because Alabama does not recognize design-defect claims in cases involving prescription drugs.

Alabama does not recognize a design-defect claim in cases involving prescription drugs, regardless of whether the claims are brought under the AEMLD or framed as negligence. Instead, prescription drugs are, for the purposes of the legal analysis, considered "inherently unsafe," *Bodie*, 236 F. App'x at 518, and this exception applies equally "to design defect claims outside of the AEMLD." *Barcal*, 2016 WL 1086028, at *3 (dismissing negligence-based design-defect theory). All of Plaintiff's design-defect claims should thus be dismissed, including her negligent design claim.

But in any event, Plaintiff fails to state a plausible claim that Pfizer negligently designed Lyrica. As with her other negligence theories, Plaintiff has not stated sufficient facts to plausibly allege, as she must, "that the product at issue is defective." *See McMahon*, 95 So. 3d at 772; *see also supra* at 7-8.

C. Plaintiff's fraud-based claims (Counts 5–8) should be dismissed because Plaintiff has not pleaded these claims with particularity.

Plaintiff asserts four fraud-based claims: fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud/deceit. To the extent these claims allege that Lyrica's warnings were inadequate, they should be dismissed for the same reasons as Plaintiff's failure-to-warn claim. *See Miller*, 2014 WL

2155020, at *5 (dismissing fraud claims as inadequately pled "to the extent that [the plaintiff] is alleging that the warnings were inadequate").

In any event, Plaintiff has not met the particularity requirement of Rule 9. A plaintiff alleging fraud "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To satisfy this particularity requirement, Plaintiff "must allege: '(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud.'" *Feldman v. Am. Dawn, Inc.*, 849 F.3d 1333, 1340 (11th Cir. 2017) (quoting *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1291 (11th Cir. 2010)). Plaintiff has not done so.

For example, in her fraudulent misrepresentation claim, Plaintiff asserts that Pfizer "falsely and fraudulently represented . . . that said product, Lyrica, has been tested and was found to be safe and/or effective for fibromyalgia." Compl. ¶ 101; *see also id.* ¶ 124. And her other allegations refer generally to "representations." *Id.* ¶¶ 102–06. These generic and conclusory allegations do not even satisfy Rule 8, much less the heightened standard of Rule 9(b). They do not identify any specific representation, the substance of what was stated, who said or concealed it, when and where a representation (or omission) was made, how it was misleading, or what Pfizer obtained as a consequence. *See Am. Dental Ass'n*, 605 F.3d at 1291.

Therefore, Plaintiff's fraudulent misrepresentation claim fails to meet the particularity requirements of Rule 9(b). Plaintiff's negligent misrepresentation claim, which also alleges that Pfizer made false representations, (Compl. ¶ 125), fails for the same reason.

Nor has Plaintiff stated a fraudulent concealment claim with particularity. Plaintiff says that Pfizer "omitted . . . material information . . . (a) that Lyrica was not safe as other forms of treatment for fibromyalgia; (b) that the risks of adverse events with Lyrica were high than those with other forms of treatment for fibromyalgia; [and] (c) that the risks of adverse events with Lyrica were not adequately tested and/or known by Defendants," among several other general allegations of omissions regarding the safety, manufacturing, and design of Lyrica. Compl. ¶ 115. But again, the Complaint does not allege what omissions were made, the time or place the omissions were made, how they were misleading, or what Pfizer gained. *See Am. Dental Ass'n*, 605 F.3d at 1291.

Plaintiff's fraudulent deceit claim is also insufficiently pleaded. As with her other fraud-based claims, Plaintiff has not alleged the substance or speaker of the statements, how the statements were misleading, or what Pfizer gained. *See id.*

D. Plaintiff fails to state sufficient facts to support viable breach of warranty claims (Counts 3, 4).

Plaintiff also fails to state plausible claims for breach of express or implied warranties, so the Court should dismiss both of Plaintiff's warranty claims.

1. Plaintiff has not identified any express warranties that were made or how they were breached.

Plaintiff fails to identify any express warranty that Pfizer allegedly breached. In Alabama, express warranties are created by "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain," or "[a]ny description of the goods which is made part of the basis of the bargain." Ala. Code § 7-2-313. Plaintiff claims that Pfizer "expressly warranted that Lyrica was safe and well accepted by users" and "expressly represented . . . that it was of merchantable quality." Compl. ¶¶ 79, 86. These unsupported allegations do not state an express warranty claim. Indeed, Plaintiff does not allege any facts suggesting that Pfizer has ever communicated with or made any direct statements to her. *See Emody v. Medtronic, Inc.*, 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003).

Plaintiff also cannot rely on Lyrica's label to allege an express warranty claim. As an initial matter, a prescription drug's label, which contains warnings about side effects that can result from the use of a drug, does not constitute a "description of goods" that creates an express warranty that the drug is "safe." *See Blackburn v. Shire US, Inc.*, No. 2:16-CV-963-RDP, 2017 WL 1833524, at *9 (N.D. Ala. May 8, 2017).[4]

[4] Indeed, a number of jurisdictions have held that an express warranty claim cannot be based on an allegation that the manufacturer warranted in its label that the drug was safe. *See, e.g.*, *In re*

Nor was any statement in the label directed to Plaintiff. Under Alabama law, the physician acts "as a learned intermediary between a drug manufacturer and a patient," because he "stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient." *Tutwiler v. Sandoz, Inc.*, 726 F. App'x 753, 755–56 (11th Cir. 2018). As a result, a drug manufacturer's duty to warn—through its product's label—"is limited to the obligation to advise the *prescribing physician* of any potential dangers that may result from the use of the drug." *Bodie*, 236 F. App'x at 519; *see also Tutwiler*, 726 F. App'x at 756. In other words, any affirmation in the label was made to the prescribing physician, not Plaintiff. All claims alleging a breach of express warranty made to Plaintiff must therefore fail.

2. Plaintiff's breach of implied warranty claim is not viable under Alabama law.

"In general, Alabama law does not recognize a cause of action for breach of implied warranty of merchantability for [prescription drugs]." *Barnhill v. Teva*

Avandia Mktg. Sales Practices & Prod. Liab. Litig., 588 F. App'x 171, 178 (3d Cir. 2014) (finding plaintiff failed as a matter of law to state an express warranty claim because the defendant disclosed the medication's "contraindications, risk factors, and potential side effects" and plaintiff did not allege defendant "made unqualified guarantees of safety or effectiveness"); *Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 257–58 (D. Conn. 2012) ("[A] drug manufacturer's representation in advertising or a warning label that a product is safe or effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects."); *In re Meridia Prod. Liab. Litig.*, 328 F. Supp. 2d 791, 818 (N.D. Ohio July 7, 2004) ("[A]ssurances that [the drug] is 'safe and effective' [are] insufficient to create an express warranty"), *aff'd sub nom. Meridia Prod. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006).

Pharms. USA, Inc., 819 F. Supp. 2d 1254, 1263–64 (S.D. Ala. May 10, 2011) (holding that prescription drug was presumed to be merchantable and fit for its intended use and dismissing implied-warranty claims because plaintiff provided no evidence to support her claim that the prescription drug was not fit). In *Bodie*, the Eleventh Circuit explained that, in the prescription drug context, Alabama courts generally "decline[] to permit [implied warranty] claims . . . to be redressed under the mechanism of the U.C.C., instead limiting the parties to remedies under products liability law." *Bodie*, 236 F. App'x at 522–23; *see also Shell v. Union Oil Co.*, 489 So. 2d 569, 571 (Ala. 1986). In other words, when a prescription drug is fit for its intended use, "courts applying Alabama law have seen fit to subsume U.C.C.-based breach of implied warranty claims into tort and product liability claims."[5] *Bodie*, 236 F. App'x at 523–24.

In her Complaint, Plaintiff alleges that Pfizer breached an implied warranty of merchantability because Lyrica was "not for merchantable quality," was "unsafe" and was "unreasonably dangerous." Compl. ¶ 94. Although Plaintiff alleges—in conclusory fashion—that Lyrica was unreasonably dangerous, she does not claim

[5] *See also, e.g.*, *Collins v. Novartis Pharm. Corp.*, No. 2:08-cv-438-MHT-PWG, 2015 WL 178157, at *9 (M.D. Ala. Jan. 14, 2015) (dismissing implied-warranty claim relating to prescription drug), *report and recommendation adopted in relevant part*, No. 2:08CV438-MHT, 2015 WL 2183700 (M.D. Ala. May 11, 2015); *McClain v. Metabolife Int'l, Inc.*, 193 F. Supp. 2d 1252, 1257–58 (N.D. Ala. Mar. 27, 2002) (dismissing implied-warranty claims as "inapposite and non-responsive to Plaintiffs' alleged injuries and claims" about risks of prescription drug).

that Lyrica failed to accomplish its intended purpose. *See In re Trasylol Prods. Liab. Litig.*, MDL No. 1928, 2010 WL 5140439, at *12–13 (S.D. Fla. Feb. 16, 2010) ("Plaintiff provides no evidence suggesting that Trasylol did not successfully reduce perioperitive bleeding. Instead, Plaintiff argues that Trasylol was commercially unfit because it was unreasonably dangerous.") (applying Alabama law). Because Plaintiff's claim is essentially that Lyrica is a defective product, she cannot bring an implied-warranty claim. Indeed, Plaintiff's allegations are indistinguishable from those that the Eleventh Circuit held did not provide "a viable cause of action [for breach of implied warranty] under Alabama law." *Bodie*, 236 F. App'x at 524 (rejecting implied warranty claim where plaintiff alleged that the drug "was not of merchantable quality, was unsafe and was unreasonably dangerous" (internal quotation marks omitted)).

The Court should dismiss Plaintiff's implied warranty claims because they are not viable under Alabama law.

E. Plaintiff fails to state sufficient facts to support a plausible claim for violations of consumer protection laws (Count 9).

The Court should dismiss Plaintiff's claim for alleged violations of consumer protection laws. Plaintiff has not alleged any specific consumer protection law that Pfizer violated, nor does she plead any facts to support this allegation. Plaintiff states only that "Defendant violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety

of Lyrica." Compl. ¶ 167. This conclusory assertion does not contain "sufficient facts to support a reasonable inference that the defendant is liable for the misconduct alleged." *See Gates*, 884 F.3d at 1296.

II. Plaintiff's claims for negligent failure to warn and design defect should be dismissed because federal law preempts both claims.

As shown above, Plaintiff has not plausibly alleged any viable claims against Pfizer. But Plaintiff's failure-to-warn and design-defect claims also should be dismissed because federal law preempts them. Thus, any attempt to amend would be futile, and Plaintiffs' claims should be dismissed with prejudice.

Under the Supremacy Clause, federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Accordingly, it has long been settled that state laws that conflict with federal law are 'without effect.'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479–80 (2013). As relevant here, "state and federal law conflict"—and state law is preempted—"where it is 'impossible for a private party to comply with both state and federal requirements.'" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

Three recent Supreme Court decisions have outlined the test for "impossibility" preemption in pharmaceutical cases: *Wyeth v. Levine*, 555 U.S. 555

(2009); *Mensing*, 564 U.S. 604 (2011); and *Bartlett*, 570 U.S. 472 (2013).[6] Together, these decisions explain that "[t]he question for 'impossibility' is whether the [defendant drug manufacturer] could *independently* do under federal law what state law requires of it." *Mensing*, 564 U.S. at 620 (emphasis added); *see also Bartlett*, 570 U.S. at 475 (citing *Mensing*). And "independently," the Supreme Court has made clear, means "*unilaterally*." *Mensing*, 564 U.S. at 620 (citing *Levine*, 555 U.S. at 573, for the proposition that preemption turns on whether "the defendant could 'unilaterally' do what state law required"). If "a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency," then those state-law obligations are preempted. *Id.* at 623–24.

Put simply, if a manufacturer cannot "independently" make the change that a plaintiff's claim would require—if FDA approval is a necessary precondition—then the claim is preempted and must be dismissed. That is the case for Plaintiff's failure-to-warn and design-defect claims here.

[6] On June 28, 2018, the Supreme Court granted certiorari in *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, which will again address the preemption of failure-to-warn claims against pharmaceutical manufacturers.

A. Federal law preempts Plaintiff's claims regardless of whether she challenges the adequacy of Pfizer's warnings before or after FDA approval.

Federal courts in this District have recently considered federal preemption of failure-to-warn claims against brand-name drug manufacturers. *See McGee v. Boehringer Ingelheim Pharms., Inc.*, No. 4:16-CV-2082-KOB, 2018 WL 1399237, at *3 (N.D. Ala. Mar. 20, 2018) (granting motion to dismiss). In *McGee*, Chief Judge Bowdre analyzed the federal statutes and regulations applicable to prescription drug manufacturers and held that federal law preempts a failure-to-warn claim unless the plaintiff plausibly alleges that the manufacturer could have changed its drug's label based on "newly acquired information" that became available after FDA approved the drug. *See id.* at *3–5. That conclusion, which is consistent with the Supreme Court's decisions in *Levine*, *Mensing*, and *Bartlett*, compels the dismissal of Plaintiff's claims here.

"At the federal level, the FDA regulates the manufacture, use, and sale of drugs." *McGee*, 2018 WL 1399237, at *3. Federal law prohibits a manufacturer from marketing a prescription drug until FDA approves the drug. 21 U.S.C. § 355; *see also McGee*, 2018 WL 1399237, at *3 ("Before the FDA permits a manufacturer to sell a new drug, the manufacturer must submit a new drug application and demonstrate that its drug is safe and effective."). As the Supreme Court has recognized, "[t]he FDA's premarket approval of a new drug application includes the

approval of the exact text in the proposed label." *Levine*, 555 U.S. at 568. Once the FDA approves a drug, "the manufacturer may only change the label after the FDA approves a supplemental application." *McGee*, 2018 WL 1399237, at *3 (citing *Levine*, 555 U.S. at 568).[7]

1. Federal law preempts any claim that Lyrica's label was inadequate when the FDA approved it.

The FDA is the "exclusive judge of [a drug's] safety and efficacy based on information available at the commencement of marketing." *In re Celexa*, 779 F.3d at 41. As a result, failure-to-warn claims "premised on the adequacy of the label as approved by the FDA when the drug was first marketed" are preempted. *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 184–85 (S.D.N.Y. 2016); *see also, e.g.*, *McGee*, 2018 WL 1399237, at *4 (holding that pre-approval failure-to-warn claim is preempted); *Bell v. Boehringer Ingelheim Pharms., Inc.*, No. 17-1153, 2018 WL 2447788, at *6 (W.D. Pa. May 31, 2018) ("Failure to warn claims based upon alleged deficiencies in the initial label are preempted."); *Mitchell v. Boehringer*

[7] In certain limited circumstances, "the manufacturer may use the 'Changes Being Effected' (CBE) process to add or strengthen warnings and precautions before the FDA approves the supplemental application." *McGee*, 2018 WL 1399237, at *3 (citing *Levine*, 555 U.S. at 568); 21 C.F.R. § 314.70(c)(6)(iii)(A). The CBE regulation applies only to labeling changes that are made "to reflect newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii); *see also, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41–42 (1st Cir. 2015); *McGee*, 2018 WL 1399237, at *3. Put simply, "[t]he FDA's drug-labelling regulations do not preempt a state duty when a plaintiff can show that the manufacturer had or should have had newly-acquired information that it could and should have used to modify its label to comply with state-law expectations." *McGee*, 2018 WL 1399237, at *4.

Ingelheim Pharms., Inc., No. 1:16-cv-02384-STA-egb, 2017 WL 5617473, at *4–5 (W.D. Tenn. Nov. 21, 2017) (claim that drug "was unreasonably dangerous because of its labeling at the time it was first marketed" is preempted); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 660 (S.D.N.Y. 2017) (holding that "federal law preempts all pre-FDA approval failure to warn and design defect claims for branded prescription medication").

To the extent Plaintiff alleges that Lyrica is unreasonably dangerous because of its label when FDA approved it, federal law preempts that claim.

2. Plaintiff has not plausibly alleged that Pfizer should have changed the Lyrica label after FDA approval.

Plaintiff also has not plausibly alleged any failure-to-warn claim that would survive preemption. Under federal law, the only state-law failure-to-warn claim that can avoid preemption is a claim that the manufacturer should have used the CBE process to *change* the label based on "newly acquired information" as defined by federal law. *See Levine*, 555 U.S. at 573; *In re Celexa*, 779 F.3d at 41 (recognizing that *Levine* "hing[es] preemption on the availability of th[e CBE] procedure in a particular case").

Plaintiff's Complaint does not identify any newly acquired information that would have allowed Pfizer to use the CBE process to change the Lyrica label after its approval. Plaintiff references two unnamed and uncited studies that "Defendant was/is aware or should have been aware of." Compl. ¶ 35. But the Complaint does

not allege when these studies were conducted, whether these studies pre-dated FDA approval, or whether the results were available before Plaintiff's alleged injury. This is insufficient to assert a non-preempted claim, because it does not plausibly allege "newly-available data that [Pfizer] had or should have had *after* [Lyrica's] approval and before [Plaintiff's] injury." *McGee*, 2018 WL 1399237, at *4–5 (holding that plaintiff failed to state a plausible failure-to-warn claim where "the complaint ma[de] no allegations about the data as it existed during the relevant time period before he had [the injury]").

Plaintiff fails to plausibly allege a non-preempted failure-to-warn claim, and the Court should thus dismiss these claims.

B. Federal law preempts any design-defect claim because it is dependent on the failure-to-warn claim.

As Pfizer has explained, Alabama does not recognize design-defect claims for prescription drugs separate from a failure-to-warn claim. *See supra* at 4. Because federal law preempts Plaintiff's failure-to-warn claim, any design-based claim likewise fails.

CONCLUSION

For the foregoing reasons, the Complaint fails to satisfy the requirements of Fed. R. Civ. P. 8(a), 9(b), and 12(b)(6) and should be dismissed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 29, 2018, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to all counsel of record.

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